Applicant: Barry N. Gellman et al. Attorney's Docket No.: 01194-448001 / 02-229

Serial No.: 10/639,945 Filed: August 13, 2003

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Amendments to the Specification:

Please replace the paragraph beginning at page 2, line 17 with the following amended paragraph:

The marker lumen can include a marker exit opening adjacent the distal end of the stylet. The stylet can include a side notch and the exit opening can be distal of the side notch. The opening can be oriented to eject a marker substantially parallel to the stylet. The stylet can include a side notch and a marker exit opening proximal of the side notch. The stylet can include a side notch and at least one marker exit opening aligned with an end of the side notch. A first exit opening can be located adjacent a first axial periphery of the sampling region and a second exit opening can be located adjacent the second exit opening a second axial periphery of the sampling region. The exit opening can be in the cannula.

Please replace the paragraph beginning at page 4, line 8 with the following amended paragraph:

FIG. 2D is a cross-sectional view taken along C-C of FIG. 2B-D-D of Fig. 2C.

Please replace the paragraph beginning at page 6, line 9 with the following amended paragraph:

Referring particularly to FIG. 2E, each marker 19, 19', 19" includes a rod portion 33, a tip portion 31, and two bands 35, 35'. The bands 35, 35' can be distinguished from the rod portion 31 33 by ultrasound, fluoroscopy, and MRI. The bands 35, 35' are fixed to and spaced along the rod portion 31 33 at a distance that approximately equals the length of the stylet notch 30 and can thus indicate the extension of a sampling site. In addition, the rod portion 31 33 maintains the bands 35, 35' in a defined orientation relative to one another so that the relative plane or perspective of the bands 35, 35' as viewed by ultrasound, etc., is detectable. In addition, the marker bands 35, 35' and the tip portion 31 have a larger cross-section than the rod portion 33, which facilitates a friction fit of the markers in the lumen 27 so that they are not prematurely ejected. The larger profile also inhibits motion of the markers after deployment in the body.

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Please replace the paragraph beginning at page 7, line 27 with the following amended paragraph:

The pusher 75 can be made of a material with sufficient column strength to transmit the force needed to eject the markers. The pusher 75 also has sufficient flexibility to follow a circuitous path in the handle. Suitable materials include metal wire made, for example, of a highly flexible metal such as nitinol, or polymer filament. The pusher 75 can be directed along a path in the handle defined, e.g., by a guide tube 25. The guide tube guides the pusher around a clockwise path and directs the pusher into the stylet slot at the proximal end of the stylet. The amount of slide motion for marker ejection can be indicated by visual marks or detents on the control handle. Slide 23 can include a lock, e.g., an element moveable in the slide path, to prevent motion of slide 23. The lock can be engaged, e.g., after one marker has been ejected, to prevent more than one marker from being placed at one biopsy site. In other embodiments, rather than following a path entirely in the control handle, the pusher may extend from the proximal end of the control handle and be urged distally by linearly pushing it into the control handle and the lumen 27.

Please replace the paragraph beginning at page 9, line 21 with the following amended paragraph:

Referring to FIGS. 5A-5C, in another embodiment, a sampling region 200 includes a stylet 210, a rotary cartridge 220, a rotary control tube 230 and a cannula 240. The stylet 210 includes a body 202 that extends to a tip 204. The tip 204 has a sample notch 30 and a marker guide 206. The cartridge 220 is rotatably positioned over the stylet body 202. The rotation control tube 240 230 extends from the proximal end of cartridge 220. The cartridge 220 has a plurality of slots 214, to accommodate markers 19. The slots 214, and the markers 19 contained within the slots, can be sequentially brought into axial alignment with the marker guide 206 on the stylet tip 204 by rotating cartridge (arrow) relative to the stylet. The cannula 230 240 has a marker opening 224 through which markers can be ejected.

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Please replace the paragraph beginning at page 9, line 30 with the following amended paragraph:

Referring to FIG. 5B, when the cannula 230 240 is extended distally to cover the notch in the stylet tip 204, the marker opening 224 of cannula 240 is vertically aligned with the marker guide 206 of stylet tip 204. The guide 206 is angled, (e.g. 25-50°) to guide a marker through the opening 224. A pusher 75 enters a slot 276 in the proximal end of the stylet body. The pusher 75 extends through the stylet body to an opening 279 proximally adjacent the cartridge 220. Referring to FIG. 5C, after a sample is taken, the pusher 75 275 can be actuated distally to slide a marker from the cartridge slot 214 to the marker guide 206 of stylet tip 204. The marker is ejected through the marker opening 224 and placed at the sampling site.

Please replace the paragraph beginning at page 10, line 8 with the following amended paragraph:

To mark another sample site, the pusher is retracted from the cartridge, and the rotation control tube 240 230 is actuated. The rotation control 240 230 includes at its distal end the cartridge 220. The tube 240 230 is arranged concentrically over the stylet body and extends proximally to the control handle and terminates in a control knob 260. The control knob 260 can protrude through the control handle body where it can be accessed by the user. By rotating the control knob 260, the user can rotate the cartridge 220 to bring marker grooves 214 sequentially into alignment with the marker guide 206. In addition, the control knob 260 can be retracted proximally to retract marker cartridge 220 proximally when the stylet is armed. The control knob 260 can be extended distally after the device has been fired to position the cartridge 220 adjacent the marker guide 206. Alternatively, the control tube and cartridge can be retracted with the stylet. In the embodiment described above, the marker is ejected at a radial location corresponding to the location of the stylet notch. In embodiments, the pusher and guide can be arranged to eject the marker at other radial locations, e.g. 180° opposite the notch.

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Please replace the paragraph beginning at page 11, line 9 with the following amended paragraph:

Referring particularly to FIG. 7A, the device is illustrated in an armed condition. An optional protective sheath 414 can be provided. The bands 410, 410' are positioned in the cannula openings 410, 410' 412, 412' and aligned with magnet poles to which they are attracted. In this example, bands are attracted to the negative poles on magnets 406', 408'.